

Kindly enter the following Amendment:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 11 of this paper.

## AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

### Listing of Claims:

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1. (Original) A sensor for the transcutaneous measurement of vascular access blood flow comprising two pairs of complementary emitter and detector elements, wherein the pairs of emitter and detector elements define two lines at right angles to each other.
2. (Original) The sensor of claim 1, wherein the emitter elements are LEDs of specific wavelengths, and the detector elements are silicon photodiode detectors that are complementary to the LEDs.
3. (Original) The sensor of claim 2, wherein the LEDs have a wavelength of 805 nm - 880 nm.
4. (Original) The sensor of claim 1, wherein one of the pairs lies to one side of the line defined by the other of the pairs, such that the two pairs of emitter and detector elements form a "T" shape.

5. (Original) The sensor of claim 4, wherein the emitter elements are LEDs of specific wavelengths, the detector elements are silicon photodiode detectors that are complementary to the LEDs

6. (Original) The sensor of claim 5, wherein the LEDs have a wavelength of 805 nm - 880 nm.

7. (Currently amended ) A sensor for the transcutaneous measurement of vascular access blood flow comprising:

a body having upper and lower surfaces;

a complementary sensing emitter/detector element pair on the lower surface of the body for positioning over and parallel to an access site; and

a complementary normalizing emitter/detector element pair on the lower surface of the body for positioning to one side of and perpendicular to the access site.

8. (Original) The sensor of claim 7, wherein the body comprises a substrate having upper and lower surfaces and circuitry associated with the emitter/detector element pairs provided on at least one of the surfaces of the substrate.

9. (Original) The sensor of claim 8, wherein the body further comprises an interior cover surrounding the substrate and the circuitry.

10. (Original) The sensor of claim 7, wherein the emitter elements are LEDs of specific wavelengths, and the detector elements are silicon photodiode detectors that are complementary to the LEDs.

11. (Original) The sensor of claim 10, wherein the LEDs have a wavelength of 805 nm - 880 nm.

a/ 12. (Original) The sensor of claim 7, wherein one of the pairs lies to one side of the line defined by the other of the pairs, such that the two pairs of emitter and detector elements form a "T" shape.

13. (Original) The sensor of claim 12, wherein the emitter elements are LEDs of specific wavelengths, and the detector elements are silicon photodiode detectors that are complementary to the LEDs.

14. (Canceled without prejudice or disclaimer)

15. (Original) A method of measuring a blood parameter transcutaneously in the vascular system of a patient having a vascular access site, using a sensor comprising two pairs of complementary emitter and detector elements, wherein the pairs of emitter and detector elements define two lines at right angles to each other, the method comprising the steps of:

placing the sensor at a measurement site on the skin of a patient with one of the pairs of emitter and detector elements parallel to the vascular access site and the other of the pairs of emitter and detector elements perpendicular to the vascular access site;

perturbing a region of the vascular system upstream of the measurement site;

using the sensor to transcutaneously measure the perturbation over a predetermined period of time at the measurement site; and

calculating the blood parameter based on the measured perturbation.

16. (Original) The method of claim 15, wherein the perturbation is accomplished by injecting a marker into an upstream end of the vascular access site.

17. (Original) The method of claim 16, wherein the marker is a saline solution.

18. (Original) The method of claim 16, wherein the marker is tagged red blood cells.

19. (Original) The method of claim 15, wherein the perturbation is accomplished by changing a parameter of the blood.

20. (Original) A method of transcutaneously measuring access blood flow in a hemodialysis circuit including a vascular access site having an arterial needle site and a venous needle site downstream of the arterial needle site, a dialyzer having an inlet and an outlet, a dialysis arterial line connecting the dialyzer inlet to the arterial needle site, and a dialysis venous line connecting the dialyzer outlet to the venous needle site, using a sensor capable of determining the relative changes in hematocrit in the access blood flowing under the skin, the sensor comprising two pairs of complementary emitter and detector elements, wherein the pairs of emitter and detector elements define two lines at right angles to each other, the method comprising the steps of:

placing the sensor on the skin with one of the pairs of emitter and detector elements parallel to and over the vascular access site downstream of the venous needle site, and with the other of the pairs of emitter and detector elements perpendicular to the vascular access site;

using the sensor to output a signal proportional to the hematocrit in the vascular access site ( $H_a$ );

recording the signal with a monitoring system associated with the sensor;

obtaining a stable baseline  $H_a$  value;

after a stable  $H_a$  is obtained, injecting a known volume (V) of a reference diluent into the dialysis venous line upstream of the sensor; and

using the signals produced from the time the diluent is injected to the time the signal returns to the baseline value to calculate access blood flow based on the ratio of percent change in hematocrit  $\Delta H$  to a time-dependent hematocrit  $H$  using the monitoring system.

21. (Original) The method of claim 20, wherein access blood flow is calculated using a transient formulation.

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22. (Original) The method of claim 20, wherein access blood flow is calculated using a steady state formulation.

23. (Original) A method of transcutaneously measuring access blood flow at an access site in a patient cardiovascular circuit using a sensor comprising two pairs of complementary emitter and detector elements, wherein the pairs of emitter and detector elements define two lines at right angles to each other, comprising the steps of:

placing the sensor on the skin of a patient with one of the pairs of emitter and detector elements parallel to and over the vascular access site and with the other of the pairs of emitter and detector elements perpendicular to the vascular access site;

infusing a specific volume ( $V_i$ ) of an indicator diluent into the patient cardiovascular circuit at the access site in the presence of a hemodialysis circuit to effect a change in a blood parameter; and

using the sensor to measure the percent change in the parameter.

24. (Original) The method of claim 23, wherein the blood parameter is selected from the group consisting of bulk density, flow energy, hematocrit, and red cell oxygen content.



25. (New) A sensor for the transcutaneous measurement of vascular access blood flow comprising:

a body having upper and lower surfaces;

sensing emitter/detector means on the lower surface of the body for positioning over and parallel to an access site for emitting and detecting light of a specific wavelength for measuring the bulk absorptivity  $\alpha$  of the volume of the access site and the volume immediately below the access site; and

normalizing emitter/detector means on the lower surface of the body for positioning to one side of and perpendicular to the access site for emitting and detecting light of the specific wavelength for measuring the absorptivity  $\alpha_o$  of a tissue region that does not contain the access.

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